

## REMARKS

### **I. Status of the Claims**

Claims 8, 10, 11, 13, 15, 18-27 and 35-55 are pending in the application. Claims 8, 10, 11, 13, 15, 18-27 stand rejected under 35 U.S.C. §102(e), and claims 35-55 stand rejected under 35 U.S.C. §103(a). The specific grounds for rejection, and applicants' response thereto, are set out in detail below.

### **II. Rejections Under 35 U.S.C. §102(e) and §103**

#### **A. Prosecution History**

Claims 8, 10, 11, 13, 15 and 18-27 stand rejected as anticipated by U.S. Patent 5,585,096 ("Martuza '096"). Claims 8, 10, 11, 13, 15 and 18-27 stand rejected as anticipated by U.S. Patent 5,585,096 ("Martuza '379"). Claims 35-55 stand rejected over U.S. Patent 5,846,945 ("McCormick '945") in view U.S. Patent 5,776,743 ("Frisch '743") and/or Martuza '096 and/or Martuza '379.

Applicants initially filed a Rule 131 declaration showing prior invention of subject matter within the scope of the claims prior to the Martuza and Frisch patent, and/or prior possession of at least as much as the relevant disclosure of the Martuza patents, which are relied upon for the rejections. In the Final Office Action of May 5, 2003, the examiner denied the relevance of this showing given that evidence of invention was allegedly narrower than that of the subject matter being claimed.

In a subsequent response, it was argued by applicants that prior possession of species is sufficient for the purposes of antedating a reference, even where the claim is broader (*i.e.*, generic) when compared to the evidence submitted. In an Advisory Action, the examiner

acknowledged the propriety of applicants' "genus-species" argument, but alleged that the submitted evidence only sufficed for conception, and that applicants had acquiesced on the issued of diligence.

A telephone call was placed to the examiner on August 25, 2003, during which it was pointed out that the previously submitted declaration actually contained evidence of reduction to practice – actual experimentation – thereby obviating the need for any discussion diligence. The examiner then indicated that applicants should submit a supplemental Rule 131 declaration with additional evidence on this point.

Subsequently, the examiner held that the supplemental Rule 131 still did not provide evidence of reduction to practice of the claimed invention, which is drawn to *in vivo* embodiments, because the evidence related only to *in vitro* experiments. Thus, the evidence was said to provide only a conception, and a showing of diligence was required to overcome the rejections. An RCE was filed on April 9, 2004, and a final Office Action was mailed on April 21, 2004, maintaining the rejections. Since the advisory action mailed on October 13, 2003, applicants have been attempting to assemble an evidentiary record to establish diligence.

#### **B. This Submission**

Applicants continue to traverse the examiner's assertion that the previous submission that the claims all require *in vivo* embodiments. For example, independent claims 23 and 46 both are generic with respect to the location of treatment, and thus the evidentiary submissions already of record fall within the scope of these claims.

However, in the interest of advancing the prosecution, applicants are submitting yet another Rule 131 declaration. In this declaration, applicants demonstrate that from a time prior

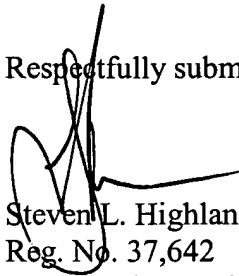
to the effective dates of either of the Martuzza patents or the Frisch patent, the inventors were diligent in pursuing a reduction to practice. Given the voluminous nature of the materials, applicants are also submitting a summary document that lists dates of relevant experiments. The undersigned submits, over his registration number, that this summary document is an accurate listing of dates on which experiments were performed.

Thus, based on the evidence of record, it is submitted that the inventors *at least* conceived of the present invention prior to publication of the cited references, and thus these references should be removed as art of record. In light of this evidence, reconsideration and withdrawal of the rejection is therefore respectfully requested.

### **III. Conclusion**

In light of the foregoing, applicants respectfully submit that all claims are in condition for allowance, and an early notification to that effect is earnestly solicited. **Should Examiner Priebe not be prepared to allow the instant claims, applicants request a telephone call to the undersigned.**

Respectfully submitted,



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